K070180

MAY 18 2007

TAB 5

510(K) SUMMARY

RESPIRONICS®

Date of Submission	17 January 2007
Official Contact / Address of Manufacturing facility	Zita A. Yurko Manager, Regulatory Affairs Respironics Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Phone: 724-387-4120 Fax: 724-387-4216 Zita.Yurko@Respironics.com
Proprietary Name	Bili-Tx
Common/Usual Name	Neonatal Phototherapy Device
Device Classification Name	Unit, Neonatal Phototherapy
Classification Reference	21 CFR 880.5700
Classification	Class II
Appropriate Classification Panel	General Hospital
Product Code	LBI
Predicate Devices	Respironics, Inc. Wallaby 3 (K991627) Natus Medical, Inc. neoBLUE cozy LED Phototherapy System (K051869) Natus Medical, Inc. Blue Light Phototherapy Unit (K022196)
Reason for submission	Modified design

Substantial Equivalence

This premarket notification submission demonstrates that the Respironics, Inc. Bili-Tx is substantially equivalent to the combination of the Respironics, Inc. Wallaby 3 (K991627), the Natus Medical, Inc. neoBLUE cozy LED Phototherapy System (K051869), and the Natus Medical, Inc. Blue Light Phototherapy Unit (K022196).

The functionality of the design of the device was verified through design verification testing. The safety of the design will be assured by the completion of IEC 60601-1 and IEC 60601-1-2 testing. Efficacy of therapy is established through peer reviewed clinical literature. The Risk Traceability Matrix provided in the Risk Analysis assures that all hazards identified by the risk analysis are successfully mitigated.

Intended Use

The Bili-Tx is intended to treat hyperbilirubinemia through phototherapy in a home or hospital/institutional environment.

Device Description

The Bili-Tx is a phototherapy light that delivers a narrow band of high-intensity blue light via blue light emitting diodes (LEDs) to provide treatment for neonatal jaundice (hyperbilirubinemia). The blue LEDs emit light in the range of 400-550 nm (peak wavelength 450-470 nm). This range corresponds to the spectral absorption of light by bilirubin, and is thus considered effective for the degradation of bilirubin[1]. The blue LEDs used by the Bili-Tx do not emit significant energy in the ultraviolet (UV) region of the spectrum or infrared (IR) region of the spectrum, so there is no concern about UV or IR exposure and excessive warming of the neonate due to use of the device.

The Bili-Tx has two different treatment options for providing phototherapy, which includes: phototherapy by fiber optic light panel that directly contacts the neonate's body and phototherapy by overhead light that is positioned over the neonate. The same Bili-Tx light source is used to provide phototherapy light for both options.

[1] Vreman HJ, et al. Light-emitting diodes: a novel light source for phototherapy. *Pediatric Research.* 1998; 44(5):804-809.

Phototherapy through Fiber Optic Light Panel

In the fiber optic light panel treatment option, the Bili-Tx consists of the light source, fiber optic cable bundle used to transmit the light from the light source to the light panel, fiber optic light panel, and disposable fiber optic light panel cover. There are two styles of fiber optic light panels that may be used, which include a longer light panel that wraps around the neonate and a shorter light panel that the neonate's body rests on.

The Bili-Tx uses the same fiber optic light panels, including the permanently attached fiber optic cable bundle, and disposable fiber optic light panel covers that were cleared with the Wallaby 3 in K991627.

This treatment option does not require protective eyeshades to be worn by the neonate receiving phototherapy as the light panel is focused by the clinician/caregiver providing therapy.

Phototherapy through Overhead Light

In the overhead light treatment option, the Bili-Tx consists of the light source and a standard intravenous (IV) pole and bracket used to support the light source over the neonate. The Bili-Tx light source used in the overhead light option is the same light source used in the fiber optic light panel option. As with all overhead phototherapy lights, protective eyeshades must be used to protect the neonate's eyes from excessive light exposure.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2007

Ms. Zita A. Yurko
Director, Regulatory Affairs
Respironics, Incorporated, Sleep & Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K070180
Trade/Device Name: Bili-Tx
Regulation Number: 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: April 25, 2007
Received: April 26, 2007

Dear Ms. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

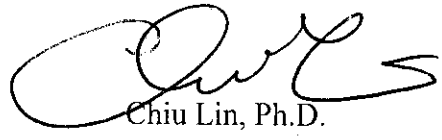
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070180

Device Name: Bili-Tx

Indications for Use:

The Bili-Tx is intended to treat hyperbilirubinemia through phototherapy in a home or hospital/institutional environment.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ADW & Anesthesiology 5/18/07

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K070180